Overview of NPPTL Research on Healthcare Worker Personal Protective Equipment

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NIOSH PPT Program Stakeholder Meeting

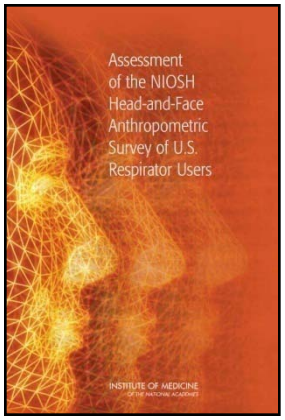
March 29th, Pittsburgh, PA

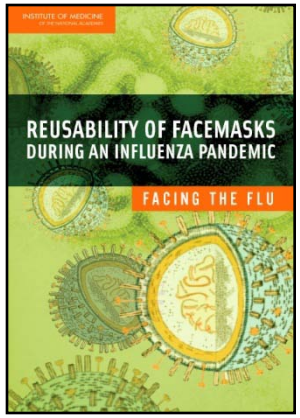
Objectives

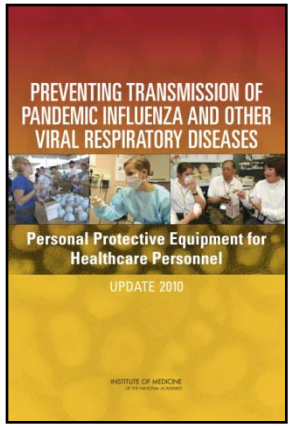
- **Provide rationale for NPPTL research projects related to personal protective equipment (PPE) for healthcare workers (HCWs)**
- **Review selected current NPPTL projects and recognize potential outcomes to the workplace**

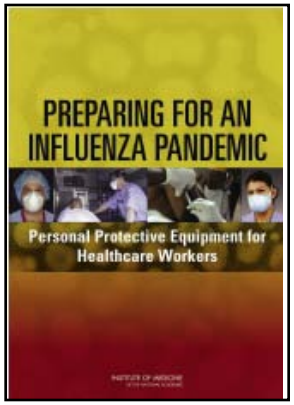
Background – Planning Efforts

- **2006 –IOM report examining issues related to the potential reuse of masks and N95 respirators in the event of an influenza pandemic**
- **2007 – IOM report to assess the NIOSH anthropometric survey**
- **2007 – IOM report on PPE for healthcare workers (HCW)**
- **2008 – NIOSH PPE for HCW Action Plan (updated 2009 and 2010)**
- **2011 – IOM PPE for HCW Update Committee**









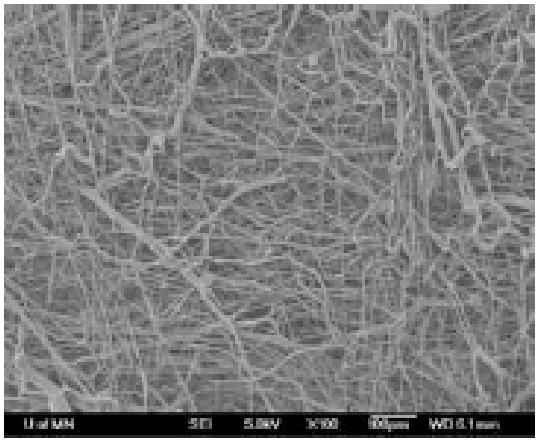
NPPTL HCW PPE Research Program Summary

- **Ensembles Research**
  - ***Surgical/isolation gowns***
- **Filtration Research**
  - ***Nanoparticles / Bioaerosols***
- **Respirator Fit Research**
  - ***Facial anthropometrics***
  - ***Frequency of fit testing***
  - Respirator fit test research (user seal check, ***novel methods***, ***multiple donnings***)
- **Respirator Comfort Research**
  - ***Physiology studies***
  - ***Project BREATHE***
- **Commit to Worker Safety and Appropriate Use of PPE**
  - ***Demo and Sentinel Surveillance***
  - Public Health Practice studies
  - Best practices, outreach
- **Respirator Performance & Usability Research**
  - ***Performance against cough generated aerosols***
  - PPE combinations
  - Respirator clinical effectiveness
- **Influenza Pandemic**
  - ***Risks of handling a contaminated respirator***
  - ***Decontamination of filtering facepiece respirators***
  - Assessing modes of transmission

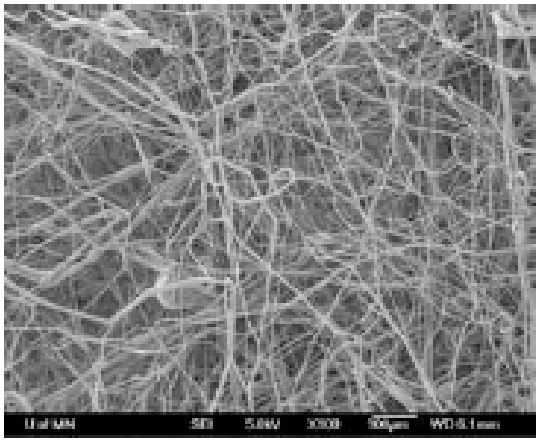
Filtration

Example Electret Filter Media

- **Melt blown - Corona charged (A)**
- **Melt blown - Highly charged (B)**
- **Extruded - Split film fiber (C)**
- **Melt blown - Highly charged (D)**

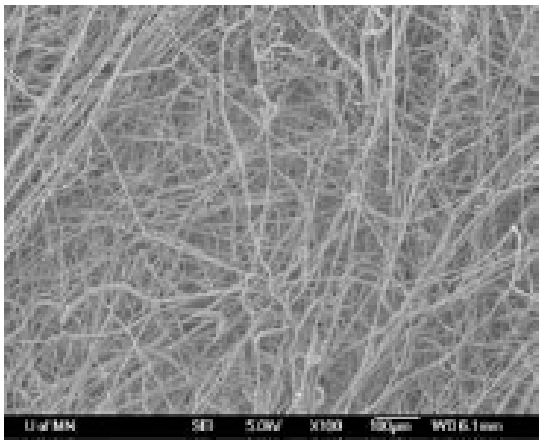


(a) Media A (× 100)



(b) Media B (× 100)

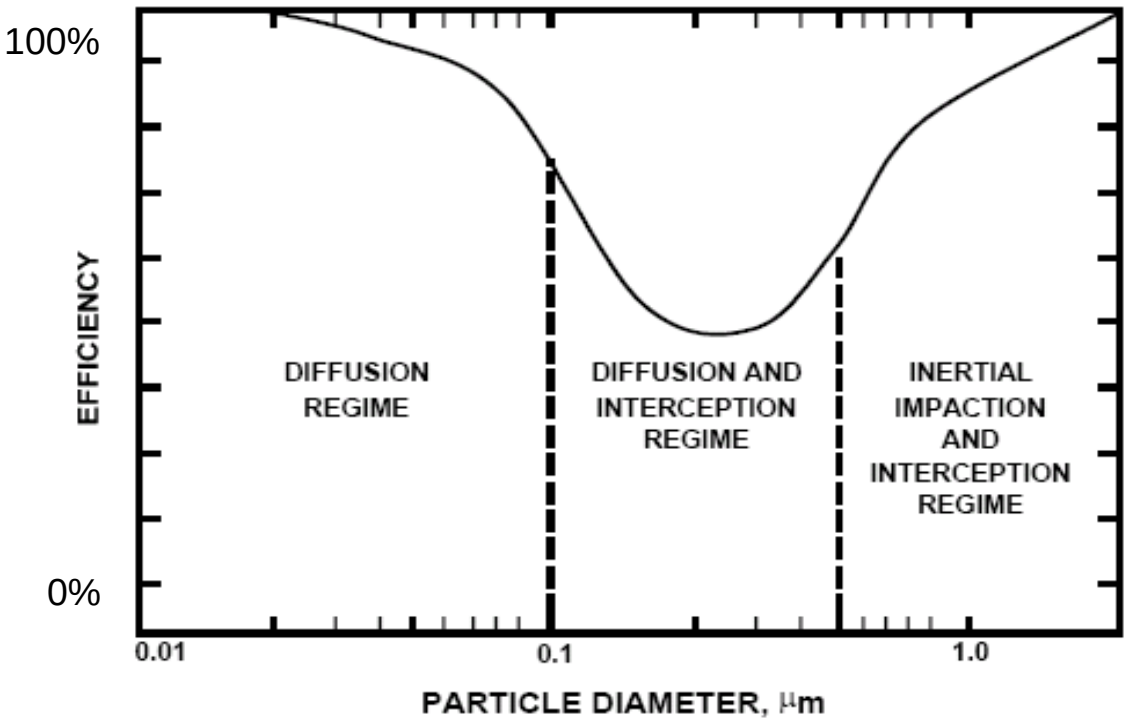
(c) Media C (× 50)

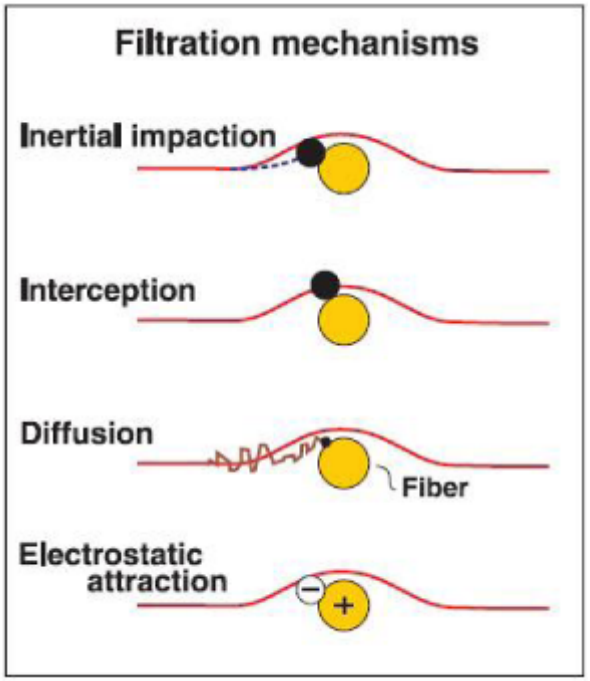


(d) Media D (× 100)

http://www.cdc.gov/niosh/npptl/researchprojects/pdfs/NanoparticleFinalReport041006.pdf

Conventional Single-Fiber Filtration Theory





Filter Efficiency Performance Results

Respirator/Mask Type	Filtration Efficiency* (%)
NIOSH N95 FFR	98.76 – 99.39
NIOSH P100 FFR	99.978 - 99.997
FDA Surgical Mask	11.94 – 98.42
Unregulated Dust Mask	12.98 - 99.00

Sample sizes: N95 filtering facepiece respirators (FFR) = 5; P100 FFR = 2, Surgical mask = 5, Dust mask = 5

*** Polydisperse Aerosol with Mass Median Diameter ~240 nm (TSI 8130, 85 L/min)**

Filtration of Aerosols with Viable H1N1 Influenza Virus

	Avg. Filtration Efficiency (N95 FFR)	Avg. Filtration Efficiency (P100 FFR)
0.8 µm bead	99.85%	99.999%
H1N1 influenza	99.27%	99.998%

- **FFRs provided equivalent filtration efficiency for inert bead and viable H1N1 influenza aerosols ($p > .05$)**
- **NIOSH approved FFRs with N95 and P100 NIOSH performance ratings provide expected levels of *filtration* performance against tissue culture adapted H1N1**

Recent Papers/Reports

- Rengasamy et al., Nanoparticle penetration through NIOSH-approved N95 filtering facepiece respirators. Journal of the International Society for Respiratory Protection, 24(1):49-59 (2007).
- Rengasamy et al., Nanoparticle filtration performance of commercially available dust masks, Journal of the International Society for Respiratory Protection, 25(1): 27-41 (2008).
- Rengasamy et al., Filtration performance of NIOSH-approved N95 and P100 filtering facepiece respirators against 4 to 30 nanometer size nanoparticles, Journal of Occupational and Environmental Hygiene, 5(9): 556-564 (2008).
- Rengasamy et al., Comparison of nanoparticle filtration performance of NIOSH-approved and CE-marked particulate filtering facepiece respirators. Annals of Occupational Hygiene 53(2): 117-128 (2009).
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- Wander J., and Heimbuch, B., Challenge of N95 and P100 Filtering Facepiece Respirators with Particle Containing Viable H1N1, Final Report, NIOSH IAA 09-42, December 2009.
- Rengasamy et al., Evaluation of Cloth Masks and Common Fabric Materials for Respiratory Protection Against 20 – 1000 nm Size Particles, Annals of Occupational Hygiene, 54(7), 789-798 (2010).
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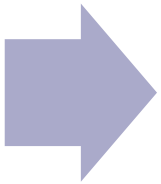
Respirator Fit Research

Science of Respirator Fit

Core Science

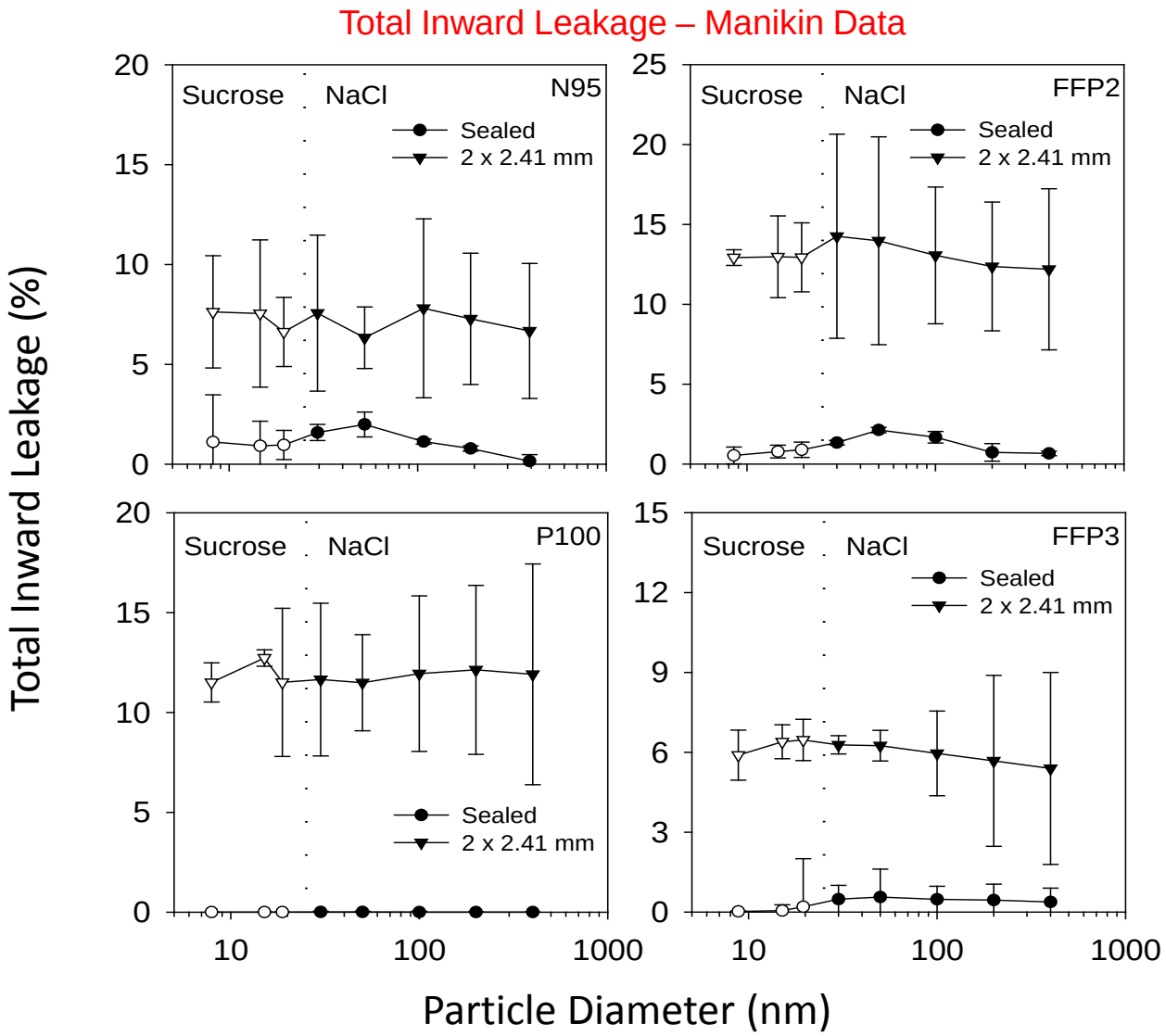
- Anthropometry
- Measurements
- Materials



Applied R&D

- Respirator Designs
- Fit Test Methods (R&D, Certification)
- Practices & Procedures for OSHA-required Initial & Annual Fit Testing

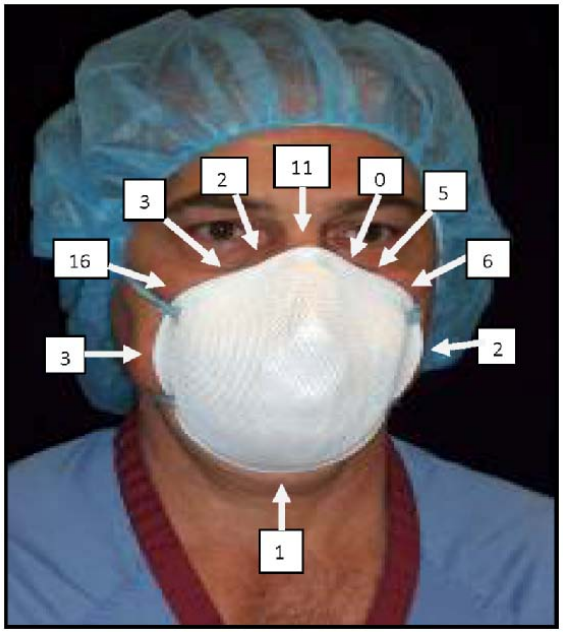
Faceseal Leakage vs. Filter Penetration



Anthropometrics & Respirator Fit

- Zhuang *et al.* reported that gender was the largest factor in face size/shape followed by race/ethnicity
- Correlation between respirator size and NIOSH respirator fit test panel face size category was found
- In another study, overall face size and nose area were found to correlate with respirator fit more than other calculated parameters
- Roberge *et al.* found that leakage detected by IRC was most common in the nose and cheekbone areas

NIOSH face size category	Respirator size with highest passing rate	Fit Test Passing Rate		
		Respirator Size		
		Small	Medium	Large
Small (NIOSH Cells 1-3)	Small	$\frac{22}{27} = 81\ \%$	$\frac{18}{27} = 67\ \%$	$\frac{7}{27} = 26\ \%$
Medium (NIOSH Cells 4-7)	Medium	$\frac{32}{48} = 67\ \%$	$\frac{40}{48} = 83\ \%$	$\frac{32}{48} = 67\ \%$
Large (NIOSH Cells 8-10)	Large	$\frac{12}{43} = 28\ \%$	$\frac{33}{44} = 75\ \%$	$\frac{36}{42} = 86\ \%$



Number of IRC detected leaks at each location

Recent Papers

- Zhuang et al. [2008]. Correlation between Respirator Fit and Respirator Fit Test Panel Cells by Respirator Size. J. Occup and Environ. Hyg 5: 617-628.
- Du et al [2008]. Head-and-Face anthropometric survey of Chinese workers. Ann. Occup. Hyg., 52: 773-782.
- Chen et al. [2009]. New respirator fit test panels representing the current Chinese civilian workforce. Ann. Occup. Hyg.,53:297-305.
- Yang et al. [2009]. Simulating the Interaction between a Respirator and a Headform Using LS-DYNA. Computer-Aided Design and Applications, 6(4): 539-551.
- Brosseau, LM. [2009] Toward Better Fitting Respirators: Summary from a Workshop and Research Roadmap, J Intl Soc Resp Prot , 26: 82-94.
- Zhuang et al. [2010] Digital 3-D headforms with facial features representative of the current U.S. workforce. Ergonomics 53:5,661-671.
- Zhuang et al. [2010] Facial Anthropometric Differences among Gender, Ethnicity, and Age Groups. Ann. Occup. Hyg. 54(4):391-402.
- Zhuang et al. [2010] Shape analysis of 3-D head scan data for U.S. respirator users. EURASIP Journal on Advances in Signal Processing, Article ID 248954, 1-10.
- Groce D et al. [2010]. Three-Dimensional Facial Parameters and Principal Component Scores: Association with Respirator Fit. J Intl Soc Resp Prot 27:1 (1-15).
- Lei et al. [2010]. Contact Pressure Study of N95 Filtering Facepiece Respirators Using Finite Element Method. Computer Aided Design and Applications, 7(6): 847-861.
- Dai et al. [2011]. Sensitivity analysis of important parameters affecting contact pressure between a respirator and a headform. Int. J. Ind. Ergon. (in press)
- Rengasamy et al. [2011], Total inward leakage of nanoparticles through filtering facepiece respirators, Ann. Occup. Hyg. (in press).

Respirator Comfort & Tolerability

Project BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees

Objective

To improve compliance among HCWs by developing information products, respirator performance requirements, and advanced technologies for the next generation of HCW respirators that are more comfortable and tolerable.

DEPARTMENT OF VETERANS AFFAIRS

Project Better Respiratory Equipment Using Advanced Technologies for Healthcare Employees (B.R.E.A.T.H.E.)

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The National Center for Occupational Health and Infection Control, [administered by the Office of Public Health and Environmental Hazards, Veterans Health Administration (VHA), Department of Veterans Affairs (VA)], is seeking to partner with commercial organizations that have respirator design and manufacturing capabilities through a Cooperative Research and Development Agreement (CRADA), under the authority of the Federal Technology Transfer Act of 1986, Public Law 99–502, 100 Stat. 1785 (codified as amended in scattered sections of 15 U.S.C. (the FTTA). The CRADA is on a research endeavor called Better Respiratory Equipment using Advanced Technologies for Healthcare Employees (or Project B.R.E.A.T.H.E.) that aims to develop a new respirator for health care workers. The genesis and emphasis of Project B.R.E.A.T.H.E. grew from recommendations issued by the Institute of Medicine in November 2007 in its report *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*, which articulates the next steps to be taken toward better respiratory protection for health care workers.

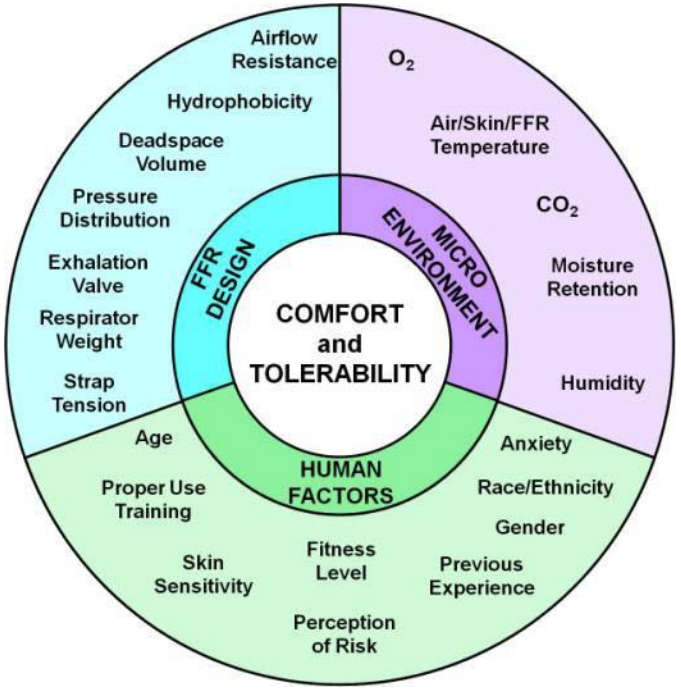
Federal Register / Vol. 74, No. 238 / Monday, December 14, 2009 / Notices

Project Tasks / Current Status

1. Interagency Working Group (Completed)
2. Research (in progress)
   a) Improving HCW compliance
   b) Comfort & tolerability research
   c) Respirator clinical effectiveness study
   d) Partnership / prototype development
3. Prototype lab & field trials (not started)
4. Commercialization / standards development (not started)

FFR Comfort / Physiology Studies

- **Many factors affect FFR comfort/tolerability**
- **No standardized test methods or performance requirements for CO_2, O_2, or comfort/tolerability**
- **In one study involving 10 HCW wearing FFR for 1 hour, Roberge *et al.* found that:**
  - FFR dead space mixed inhalation/exhalation O_2 and CO_2 concentrations do not meet OSHA ambient workplace standards
  - Heart rate, respiratory rate, tidal volume, minute volume, O_2 saturation, transcutaneous CO_2 levels, comfort/exertion scores between controls and FFR were not statistically different
- **Current study seeks to develop multivariate models to correlate FFR design features, FFR microenvironment, and human factor data with subjective responses**



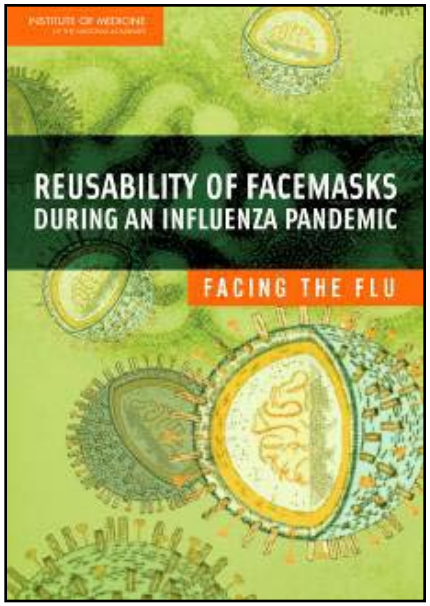
Recent Papers

- Roberge R [2008]. Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life versus increased user burden. Journal of Public Health Management 14(2) E19-E26.
- Vojtko et al., [2008]. Effect on breathing resistance of a surgical mask worn over an N95 filtering facepiece respirator". Journal of International Society for Respiratory Protection 25:1-7.
- Roberge R [2009]. Physiological burden associated with the use of filtering facepiece respirators (N95 masks) during pregnancy. Journal of Women's Health 18(6): 819-826
- Monaghan et al., [2009]. Thermal imaging comparison of maximum surface temperatures achieved on N95 filtering facepiece respirators with and without exhalation valves at sedentary breathing volumes. Journal of the International Society for Respiratory Protection 26(1), 12-19.
- Williams WJ [2010]. Physiological response to alterations in O_2 and CO_2: relevance to respiratory protective devices. J Intl Soc Resp Prot 27(1), 27-51.
- Roberge et al., [2010]. Physiological impact of the N95 filtering facepiece respirator on healthcare workers. Respiratory Care 55:5, 569-577.
- Roberge et al., [2010]. Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers. Respirology 15:516-521.
- Roberge et al., [2010]. Reusable elastomeric air-purifying respirators: Physiological impact on healthcare workers. Am J Infec Control 38:381-6.
- Roberge et al.,. [2010] Effect of exhaled moisture on breathing resistance of N95 filtering facepiece respirators. Annals of Occupational Hygiene. 54(6), 671–677.

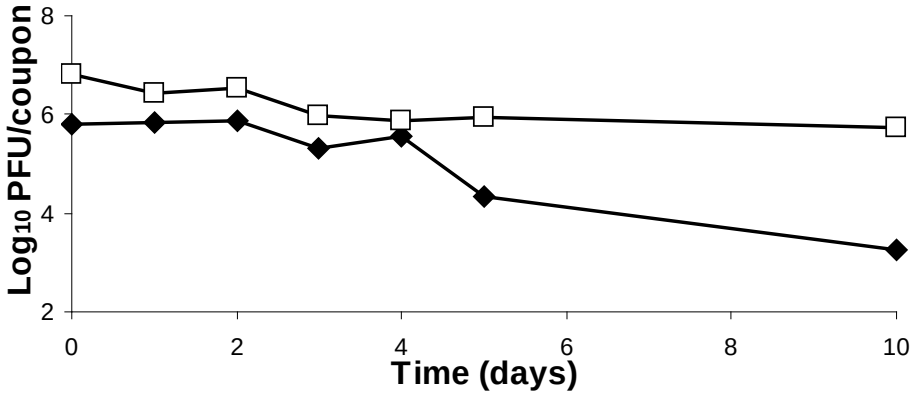
Influenza Pandemic

Critical Questions

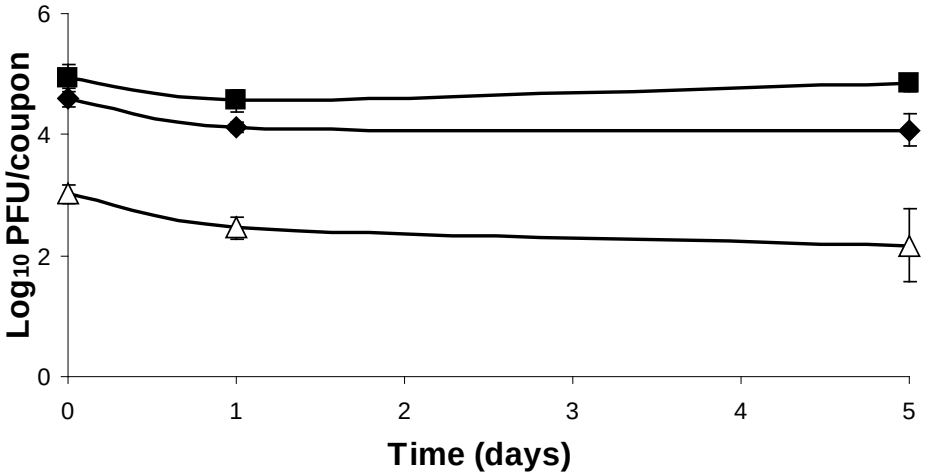
- **Can infectious aerosols survive on FFRs long enough to present a fomite hazard?**
- **Would FFRs that incorporate antimicrobial technologies prevent the FFR from becoming a fomite?**
- **Would the use of biological decontamination methods allow for disposable FFRs to be reused?**
  - Can decontamination methods render infectious material on an FFR inactive?
  - Does decontamination affect FFR performance?



Long-Term Storage Results



Survival of MS2 deposited as droplet nuclei (♦) or droplets (□) on FFR coupons. Viable MS2 were enumerated after storage.

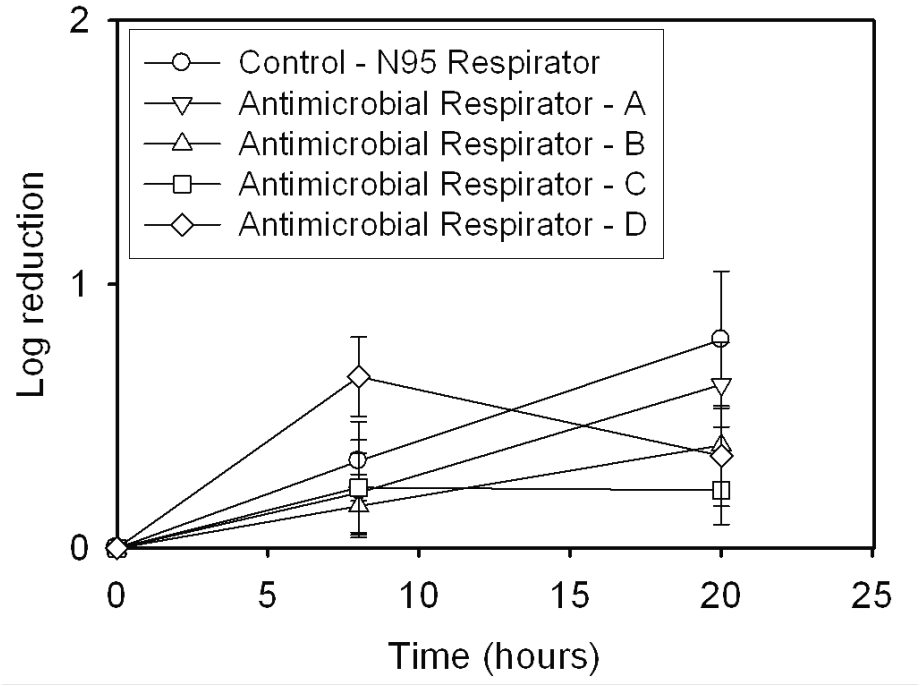


Survival of MS2 deposited as droplet nuclei on the exterior layers (♦), internal filtering media (■) and interior layers (Δ) of FFR coupons. Viable MS2 were enumerated for each layer after storage.

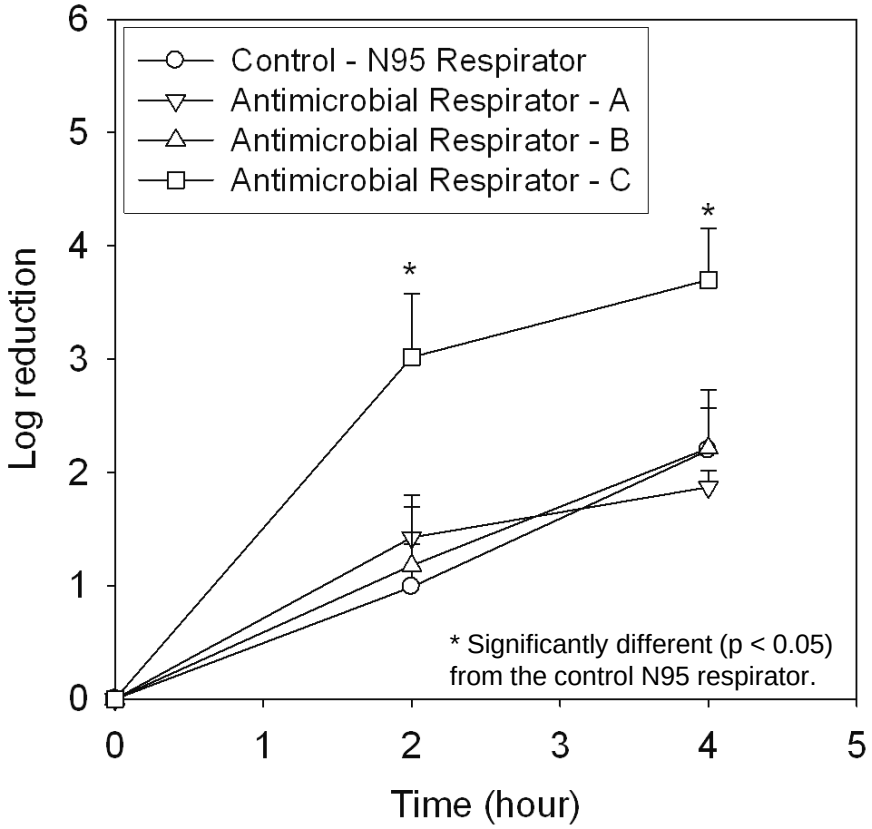
- All coupons had detectable levels of MS2 after 10 days of storage at 22°C and 30% RH.
- MS2 survivability was similar for each layer
- FFRs have the potential to serve as a fomite

Antimicrobial Respirators

22ºC and 30% RH



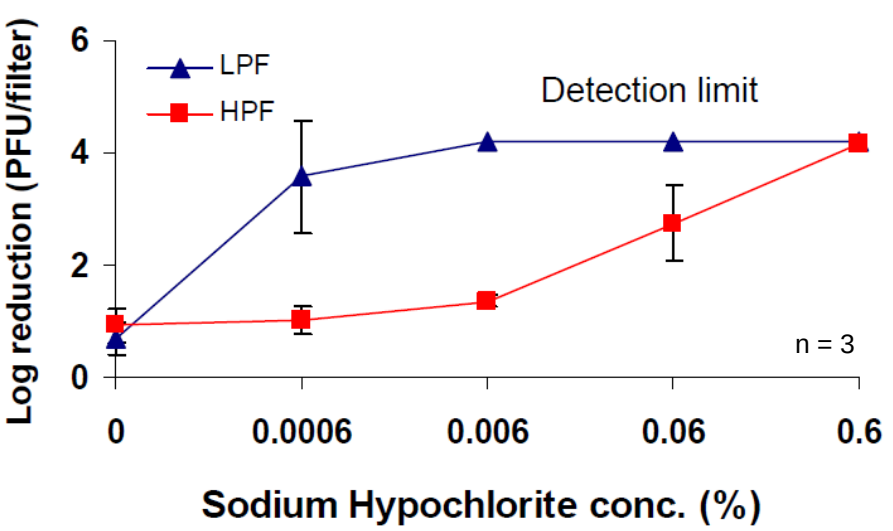
37ºC and 80% RH



Antimicrobial respirator effectiveness is dependent upon the antimicrobial agent and storage conditions

Effectiveness of Biological Decontamination Methods

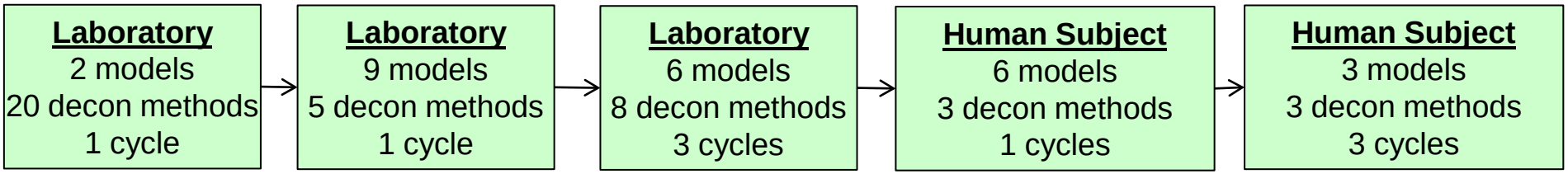
- **Key findings from several studies include:**
  - Decontamination efficacy increases as a function of dose and time
  - Increased organic load (protection factor) in the MS2 viral aerosol challenge reduces decontamination efficacy some methods (e.g., bleach, UVGI), but not others (e.g., heat, steam)
- **Project resulted in two test methods: ASTM E2720-10 and E2721-10**



LPF = low protection factor (organic load)
HPF = high protection factor (organic load)

Does Decontamination Affect FFR performance?

Experimental Design (5 phases)



- **Summary of Findings:**
  - FFRs tested have differences in their design (e.g., # of layers, face seal enhancements) and materials (e.g., hydrophobicity), which affects their ability to withstand some decon conditions
  - Autoclave, >100º C heat, isopropyl alcohol, microwave (dry heating), hydrogen peroxide gas plasma, and soap & water caused significant physical or filter degradation to some or all of the models tested, while bleach had noticeable odor and some off-gassing
  - FFRs treated by UVGI, hydrogen peroxide vapor, microwave generated steam, moist heat incubation, and ethylene oxide had expected levels of laboratory filtration performance
  - UVGI, microwave generated steam, and moist heat decontamination resulted in clinically insignificant changes in fit, odor, comfort, and donning ease

Concept for Regulatory Implementation

- **Decontamination capability is not expected to be a requirement (optional)**
  - Model dependent
  - Avoids product availability concerns
  - Manufacturer determines capabilities by including decontamination procedure instructions
- **Announcement of research results does not constitute approval**

Recent Reports/Papers

- **Viscusi et al. Effect of Decontamination on the Filtration Efficiency of Two FFR Models. J. Int. Soc. Resp. Prot., (2007) 24: 93-107.**
- **Richardson et al. Final Report for Reaerosolization of Viruses from NIOSH-Certified Filtering Facepiece Respirators. May 2008.**
- **Viscusi et al. Evaluation of the filtration performance of 21 N95 FFRs after prolonged storage. Am. J. Infect. Control, (2009) 37:381-386.**
- **Viscusi et al. Evaluation of Five Decontamination Methods for FFRs. Ann. Occup. Hyg., (2009) 53: 815-827.**
- **Fisher et al. Development of a test system to evaluate procedures for decontamination of respirators containing viral droplets. Appl. Environ. Microbiol., (2009) 75: 1500-1507.**
- **Vo et al. Development of a Test System to Apply Virus Containing Particles to FFRs for the Evaluation of Decontamination Procedures. Appl. Environ. Microbiol., (2009) 75: 7303-7309.**
- **Rengasamy et al. Evaluation of the survivability of MS2 viral aerosols deposited on FFR samples incorporating antimicrobial technologies. Am. J. Infect. Control, (2010) 38: 9-17.**
- **Fisher E, Shaffer R, Survival of Bacteriophage MS2 on Filtering Facepiece Respirator Coupons. Journal of Applied Biosafety 15(2), 71-76 (2010).**
- **Bergman et al, Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators, Journal of Engineered Fibers and Fabrics 5(4), 33-41 (2010).**
- **Fisher, E., and Shaffer, R.E., A Method to Determine the Available UV-C Dose for the Decontamination of Filtering Facepiece Respirators, J. App. Microbiol.,, 110(1), 287-295 (2011)**
- **Viscusi et al., Impact of Three Biological Decontamination Methods on Filtering Facepiece Respirator Fit, Smell, Comfort, and Donning Ease, Journal of Occupational and Environmental Hygiene (in press)**
- **Fisher et al, "Evaluation of Microwave Steam Bags for the Decontamination of Filtering Facepiece Respirators", PLOSone (in press)**

Concluding Remarks

- **NPPTL has an active research program, involving numerous partners, with current and planned projects related to filtration, respirator fit, comfort/tolerability, understanding barriers to proper use, performance, and specific issues related to Pandemic Influenza**
- **Priority gaps in the PPE for HCW action plan are being addressed**
- **Next steps – continue the respiratory protection research projects in accordance with the action plan and expand the NPPTL protective clothing laboratory capabilities**

Acknowledgments

- **NPPTL Research Staff Working on These Projects:**
  - TRB Respiratory Protection Research Team: Ziqing Zhuang, Samy Rengasamy, Evanly Vo, Dennis Viscusi, Ed Fisher, Stacey Benson, Jessica Williams, Stephanie Lynch
  - TRB Research Medical Officer: Ray Roberge
  - TRB Human Performance Research Team: Nina Turner, Jon Williams, Aitor Coca, Kenny Kim, Jeff Powell
  - TRB Protective Clothing & Ensembles Team: Bill Monaghan
  - URS Staff: Ben Eimer, Mike Bergman, Andy Palmiero
  - Health Communications Team: Debbie Novak
  - Statistical Support: Kim Faulkner
- **Other collaborators**
  - Air Force Research Laboratory, Battelle Memorial Institute

Thank you

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Quality Partnerships Enhance Worker Safety & Health

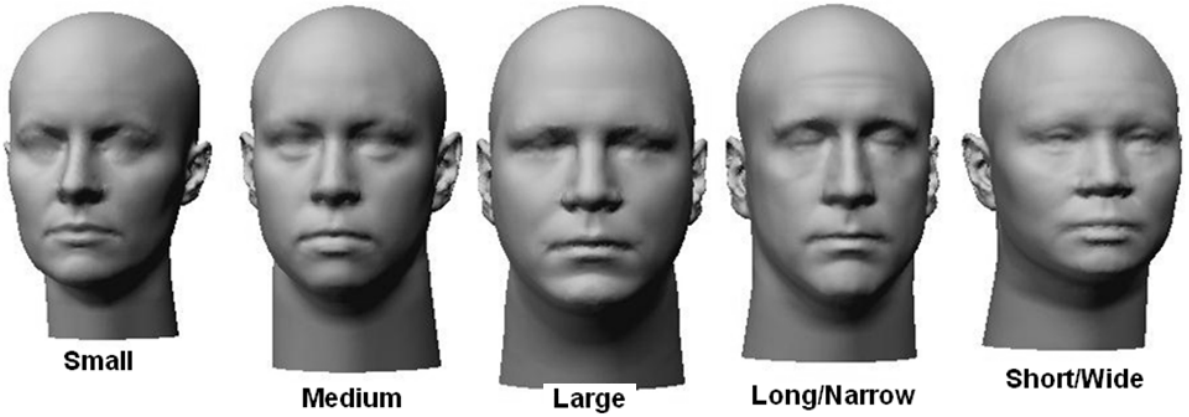


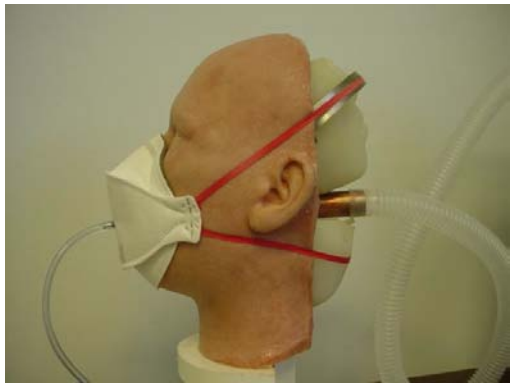

Disclaimer:

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

Representative Headforms for Respirator Testing

- **Digital 3-D headforms created for US and for Chinese workers**
- **Next, combine with skin-like surfaces to mimic respirator fit on a human**
- **Ultimate goal – fit test panel of articulated manikins**





Performance & Usability

Effectiveness of Respirators in Clinical Settings

- **Many laboratory studies available to show higher levels of protection provided by filtering facepiece respirators (FFRs) compared to surgical masks (SMs), but few studies have been in clinical settings**
- **Loeb et al (2010) study***
  - Found that among 446 nurses in Ontario tertiary care hospitals, incidence of laboratory confirmed influenza was similar in nurses wearing SMs vs. FFRs
  - Statistical criterion of non-inferiority was met
- **Study limitations made acceptance among some stakeholder groups difficult**

* Loeb, Dafoe, Mahoney, et al, Surgical Mask vs. N95 Respirator for Preventing Influenza Among Health Care Workers: A Randomized Trial, JAMA. 2009;302(17):1865-1871

Respiratory Protection Effectiveness Clinical Trial (ResPECT)

- **Objective –** Determine if the incidence of *lab confirmed influenza* is lower among HCWs wearing FFRs (arm #1) vs. those who wear SMs (arm #2)
- **Background –** CDC funded the VHA and Johns Hopkins University (JHU) to conduct this study. NIOSH manages the effort within CDC.
- **Approach –** prospective, unblinded, cluster randomized evaluation
- **Year 1 focus – pilot study at JHU (Jan 2011-April 2011)**
  - 116 HCWs enrolled; nasal swab samples are collected weekly; subjects are asked to complete daily and weekly diaries; Trained researchers observing clinics to determine adherence
- **Years 2 – 4+ – expand to multiple clinical locations**
  - 4 years of data collection with 116 clusters is expected to provide sufficient power to detect a 25% reduction in lab confirmed influenza among subjects in the FFR arm vs. the surgical mask arm